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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MARVICH, MARIA

ART UNIT PAPER NUMBER

1636

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/758,515

Applicant(s)

BRAMBILLA ET AL

Examiner

Maria B. Marvich, PhD

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/24/05; 12.27/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5 and 10 is/are rejected.
- 7) ☒ Claim(s) 2-4,6 and 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

This Office Action is in response to an amendment filed 3/24/05 and 12/27/04 and a Declaration filed 12/27/04. Claims 8 and 9 have been cancelled. Claims 1, 2, 4, 5, 7 and 10 have been amended. Claims 1-7 and 10 are pending in this application.

Response to Amendment

Any rejection of record in the previous action not addressed in this office action is withdrawn. There are new grounds of rejection herein and therefore, this action is non-final.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1, 5 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Gilbert et al (US 2002/0034805; see entire document). **This rejection is maintained for reasons of record in the office action mailed 8/24/04 and restated below.**

Gilbert et al teach expression of fusion proteins that find use in the enzymatic synthesis of oligosaccharides (see e.g. paragraph 0055). Expression vectors encoding said proteins are transformed into host cells such as *Zygosaccharomyces bailii* (see e.g. paragraph 0123) by means of electroporation of the nucleic acid (see e.g. paragraph 0117). The procedures for purification of proteins from cell culture are well known in the art to a person of skill in the art at the time of filing of the instant invention as evidenced by the extensive references to procedures Gilbert et al provided in paragraph 0126. It was well known in the art that electroporation of yeast is

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performed in the presence of monovalent ions and reducing agents (see e.g. Thompson et al. Yeast Vol. 14:565-571) as recited in claim 10. Claim 5 is included in the rejection because any single nucleotide or dinucleotide or even greater combinations of nucleotides from pSB2 are identical to a nucleotide or dinucleotide or even greater number of nucleotides from the expression vector of Gilbert et al.

Claims 1, 5 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Sjoberg (US 6,500,661; see entire document). **This rejection is maintained for reasons of record in the office action mailed 8/24/04 and restated below. Upon reconsideration, the rejection is made under 102(e) and not 102(b) and therefore this is a new rejection.**

Sjoberg teaches the transformation of *Z. bailii* with recombinant GDP-fucose synthesizing enzymes (see bridging paragraph column 14-15). Following expression, the enzyme is purified (or recovered) (see column 18, line 35-54). Eukaryotic cells are transformed by electroporation (see column 18, line 35-41). It was well known in the art that electroporation of yeast is performed in the presence of monovalent ions and reducing agents (see e.g. Thompson et al. Yeast Vol. 14:565-571) as recited in claim 10. Claim 5 is included in the rejection because any single nucleotide or dinucleotide or even greater combinations of nucleotides from pSB2 are identical to a nucleotide or dinucleotide or even greater number of nucleotides from the expression vector of Sjoberg.

Response to Argument

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Applicants traverse the claim rejections under 35 U.S.C. 102 on pages 7-8 of the amendment filed 12/27/04. Applicants argue that a Declaration has been submitted which demonstrates that the instant invention was reduced to practice between January 1, 1996 and September 11, 1998. Applicants argue that this demonstrates that the invention was made prior to the effective date of Gilbert et al, December 14, 1998, and Sjoberg, January 14, 1999. Applicants correctly indicate that Sjoberg should not have been rejected under 102(b). This rejection has been correctly identified as a 102(e) rejection.

In the Declaration under 37 CFR 1.131 filed 12/27/04, Dr. Porro reports that the work depicted in PCT Published Application WO 99/14335 was performed under his direction between January 1, 1996 and the PCT filing date of September 11, 1998. Furthermore, Dr. Porro indicates what sections teach a process of transformation and expression in *Z. bailii* as recited in the instantly rejected claims.

Applicants' arguments filed 12/27/04 and the Declaration filed on 12/27/04 under 37 CFR 1.131 has been considered but is ineffective to overcome the Gilbert et al and Sjoberg et al references. First, the earliest effective date that can be attributed to the WO document is September 11, 1998 is ineffective in overcoming the reference dates of Gilbert et al and Sjoberg et al. Applicants have incorrectly indicated these dates as December 14, 1998 and January 14, 1999. The MPEP teaches the following with regard to establishing the 102(e) date. "The 35 U.S.C. 102(e) date of a reference that did not result from, nor claimed the benefit of, an international application is its earliest effective U.S. filing date, taking into consideration any proper benefit claims to prior U.S. applications under 35 U.S.C. 119(e) or 120 if the prior application(s)". Under these guidelines, the earliest effective filing date of Gilbert et al is

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December 15, 1997 and of Sjoberg is January 15, 1998. Dr. Porro does not establish that these dates are antedated by WO 99/14335.

Secondly, should applicant rely upon the filing date of the foreign application to which WO 99/14335 claims benefit, a translation would be required. However, should the translation of this document reveal what is already disclosed in the WO 99/14335 document, the evidence would be insufficient to establish diligence from a date prior to the date of reduction to practice of the Gilbert et al and Sjoberg et al references to a constructive reduction to practice or filing of the application. 37 CFR 1.131(b) teaches "(T)he showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application. Original exhibits of drawings or records, or photocopies thereof, must accompany and form part of the affidavit or declaration or their absence satisfactorily explained." Applicants have not demonstrated diligence from filing of the foreign application of September 12, 1997 to construction reduction to practice corresponding to filing of the instant application on January 15, 1999. Due to a lack of diligence of filing, any overlap in the teachings of MI97A00280 and WO 99/14335 to be used to antedate Gilbert et al and Sjoberg et al would be ineffective.

Conclusion

Claims 1, 5 and 10 are rejected.

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Claims 2-4, 6 and 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1636

May 19, 2005



JAMES KETTER
PRIMARY EXAMINER